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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GIBSON, ROY DEAN

ART UNIT PAPER NUMBER

3739

DATE MAILED: 04/06/2004

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

Applicant(s)

10/069,649

NASHEF ET AL.

Examiner

Art Unit

Roy D. Gibson

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-16 and 19-28 is/are rejected.
- 7) ☐ Claim(s) 3, 17 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the examiner suggests the insertion of "includes" or "comprises" after "device" in line 1.

Claim 14 recites the limitation "resistor structure" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-11, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Quinn et al. (6,387,052).

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As to claims 1, 2 and 4, Quinn et al. disclose a catheter having a distal end and a wall, the catheter comprising a heat transfer device (Figure 4, # 400) located near its distal end, wherein the heat transfer device is engaged with the catheter wall and wherein the device is a flexible film having at least one electrical resistor flow path, which film is locatable around the catheter wall and wherein the at least one electrical resistor flow path is located on a plastic film backing (col. 1, lines 10-16, col. 3, lines 27-40, col. 5, line 55-col. 6, line 34, col. 10, lines 41-55 and col. 11, lines 29-37).

As to claims 5 and 6, these are product-by-process claims in which patentably is determined based on the product itself, not the process by which it was made and are rejected because Quinn et al. disclose at least one electrical path as detailed above (see MPEP 2113).

As to claim 7, Quinn et al. further disclose the heat transfer device is disposed directly onto or is a part of the catheter wall (col. 11, lines 39-46).

As to claims 8-11, these are product-by-process claims in which patentably is determined based on the product itself, not the process by which it was made and are rejected because Quinn et al. disclose at least heat transfer devise disposed on the wall of the catheter as detailed above (see MPEP 2113).

As to claim 13, Quinn et al. disclose the heat transfer devise includes at least one temperature sensor (col. 18, lines 27-39).

As to claim 14, Quinn et al. disclose at least one insulator layer (outer sheath # 404) is located over the electrical resistor flow path (col. 10, lines 51-65).

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Khalil (5,056,526). Khalil discloses a catheter having a distal end with a single lumen and a wall with an outside diameter of 5F, the catheter comprising a heat transfer device (Figure 1, A) located near its distal end, wherein the heat transfer device is engaged with the catheter wall and inherently the diameter of the lumen is about 0.5-0.7 mm.

Claims 19-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Saad (5,727,553). Saad discloses a catheter (Figure 3A) having a wall with at least one metal wire or a set of metal copper wires in a portion of the wall (conductors 32 and 32' and col. 2, lines 17 -23) and also Figure 6 (col. 5, line 65-col. 6, lines 14, conductors 64 and 64'). Further to claim 21, Saad discloses the wire is molded within the catheter wall rather than co-extruded with it (col. 6, lines 9-14), however, this is a product-by-process claim in which patentability is determined based on the product itself, not the process by which it was made and are rejected because Quinn et al. disclose at least one electrical path as detailed above (see MPEP 2113).

Further to claim 24, Saad discloses the lead wires (64 and 64') are easily exposable (Figure 6A).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn et al. in view of Nashef et al. (5,682,899).

As to claim 15, Quinn et al fail to disclose the insulator layer is made from parylene C. But, Nashef et al. disclose a catheter for the same application in which the heat transfer device is covered with an insulator made from parylene C because it binds well to a variety of surfaces, transfers heat and does not absorb moisture (col. 7, line 66-col. 8, line 13). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Quinn et al., as taught by Nashef et al., to provide an alternative equivalent insulation layer material made from parylene C in order to take advantage of its properties recited above.

As to claim 16, Quinn et al fail to disclose the heat transfer device includes an outwardly located layer of material of silver or gold. But, Nashef et al. further disclose the catheter includes a biocompatible material layer made of gold or silver (col. 7, lines 3-17). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to further modify the device of Quinn et al., as taught by Nashef et al., to provide another protective and heat conductive layer over the heat transfer device.

Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saad based on the case law "duplication of parts" (MPEP 2144.05 VI, B), i.e., and that it would be have been obvious that more sets of wires could be molded, etc. into the catheter wall, not only one as required. See also Griffin (6,144,870) who discloses two sets of lead wires extrudes with the polymeric body of a catheter (col. 3, lines 21-41).

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn et al. in view of Saad. Quinn et al. disclose the lead wires are provided in separate lumens within the catheter, but Saad teaches the alternative equivalent means of incorporating the lead wires within the walls of the catheter as detailed above. Further to claim 26, it would have been obvious to make the catheter of Quinn et al. approximately 3-5 F, since the application is insertion of the catheter into the vasculature of a patient.

Allowable Subject Matter

Claims 3 and 17-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Champeau (6,400,976) discloses a catheter with thin film electrodes; Quinn et al. (5,857,976) discloses the same invention as P/N 6,387,052 above; and Hughes (5,474,080) discloses a catheter for monitoring cardiac output.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 703-308-3520. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703-308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Roy D. Gibson
Primary Examiner
Art Unit 3739

March 29, 2004